

- f. stapling the surrounding portion of tissue; and
- g. resecting the selected portion of tissue from the surrounding portion of tissue.

REMARKS

Claims 36 - 51 remain pending in this application. Claim 36 has been amended to more particularly point out and distinctly claim the subject matter of the invention. In view of the above amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 36 - 38 and 40 - 43 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta (U.S. Patent No. 5,389,098) in view of Sauer (U.S. Patent No. 5,562,694). The Examiner stated in support of the rejection that Tsuruta shows a stapling assembly substantially as claimed except for the grasper for drawing tissue into the cutting zone. The Examiner further stated that Sauer shows a grasper as claimed and that it would have been obvious to have combined the stapling assembly of Tsuruta with the grasper of Sauer to achieve the claimed invention.

Claim 36 recites an apparatus for resecting tissue within a body lumen, comprising “an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle.”

In contrast, Tsuruta shows various rigid surgical instruments which are inserted into body cavities *via incisions made in body walls*. (Col. 2, lines 44-46). The Examiner has dismissed

applicants arguments concerning the unsuitability of the Tsuruta devices for intra-luminal use by stating that all of the rigid devices *could* be placed entirely within a body lumen and that any device has some degree of rigidity. As noted previously, none of these devices could be placed entirely within a body lumen as they would destroy any lumen into which they were inserted. It is respectfully submitted that the Examiner has provided no support for his statement that the capsule of Tsuruta could clearly “be placed entirely within a body lumen.” Applicant disagrees with this assertion and respectfully requests that the Examiner indicate which body lumen may be suitable to receive the device of Tsuruta and describe the manner in which this device may be inserted therein. It is respectfully submitted that none of the cited references includes any such teaching.

In addition, claim 36 has been amended to recite “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle.” It is respectfully submitted that no such flexible member is shown or suggested by Tsuruta.

The Examiner has indicated that the “rigidity” or “flexibility” of various elements is a relative term and that the rigidity of the components of the devices of the cited references does not make them unsuitable for use with flexible endoscopes. However, the applicant respectfully submits that, in view of the description in the specification, the term flexible would clearly be understood by those of skill in the art to mean a degree of flexibility allowing the device to pass along the path of a body lumen bending as the lumen curves without damaging the luminal tissue. It is respectfully submitted that, even if the rigid components of the devices in the cited references possess some degree of flexibility, none of these is flexible as that term is used in this application.

As described previously, the devices of Tsuruta include a stapling mechanism at the distal end of a rigid shaft which, when in an operative position, extends from outside the body, through an incision into a body cavity. Therefore, it is respectfully submitted that none of the Tsuruta

devices includes an operating capsule as recited in recited in claim 36.

Similarly, Sauer shows a rigid instrument which is not coupleable to a flexible endoscope and which includes no capsule which is locatable entirely within a body cavity. Although Sauer describes the device as useful in endoscopic surgical procedures, it is clear that the device is not intended for use with a flexible endoscope. Specifically, Sauer states that endoscopic procedures involve “incising through body walls for examining, viewing and/or operating on various bodily organs or structures” with a trocar being employed to create the incision and tubes being inserted through the incision and left in place in the abdominal wall so that tools may be inserted therethrough. (Col. 1, lines 17-24). Thus, the elongated body portion 14 is not flexible as that term is used in this application and includes no “flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle,” as recited in claim 36.

For these reasons, it is respectfully submitted that neither Tsuruta nor Sauer either show or suggest an apparatus for resecting tissue within a body lumen, comprising “an operating capsule including a coupling structure for selectively coupling to a flexible endoscope, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle” as recited in claim 36. Furthermore, both of these references are specifically directed to rigid devices for use with open surgery and therefore teach away from the a device for use with a flexible endoscope.

It is therefore respectfully submitted that claim 36 is not obvious over Tsuruta and Sauer either taken alone or in combination and that this rejection should be withdrawn. Because claims

37, 38 and 40 - 43 depend from and, therefore, include all of the limitations of claim 36, it is respectfully submitted that these claims are also allowable.

Claim 39 stands rejected under 35 U.S.C. § 103 as obvious over Tsuruta in view of Sauer as applied to claim 36 in further view of Bessler (U.S. Patent No. 5,197,649). The Examiner stated, in support of the rejection, that Tsuruta in view of Sauer show the invention as claimed with the exception of the endoscope and that Bessler shows an endoscope as claimed. However, as indicated above, Tsuruta and Sauer do not show the invention as claimed in claim 36 and Bessler fails to cure the defects noted above in regard to this rejection of claim 36.

Specifically, as discussed above in regard to claim 36, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and that these differences taught away from combinations with flexible endoscopes. Clearly none of the references provides the motivation for such a combination. Specifically, the device of Bessler is intended to eliminate the type of open procedures for which the devices of Tsuruta and Sauer are designed and adding a flexible endoscope as shown to either of these devices (or a hybrid thereof) would bring back the problems that the Bessler device is attempting to address. Specifically, there is clearly no motivation in either Tsuruta or Sauer to combine with a flexible endoscope as the flexibility and steering capabilities of such an endoscope would be useless within the rigid bodies of these devices. And the device of Bessler is an attempt to eliminate the need for incisions in performing operations such as anastomoses of the colon. Thus, combining the teaching of Bessler with any rigid device is completely contradictory to the teachings of that reference. Among the disadvantages of prior devices discussed, Bessler states that “[m]any of the available devices have a rigid structure which preclude (sic) their application for other than straight intestines.” Thus, the combination of this device with a rigid structure is clearly taught away from by Bessler.

It is therefore respectfully submitted that none of the cited references provides any motivation for the combination suggested by the Examiner and that, therefore, this rejection is based on an impermissible hindsight reconstruction of the invention. For this reason and for the

reasons stated above in regard to claim 36, it is respectfully submitted that claim 39 is not rendered obvious by Tsuruta, Sauer and Bessler and that this rejection should be withdrawn.

Claims 44 - 48 stand rejected under 35 U.S.C. § 103 as obvious over Tsuruta in view of Bessler. The Examiner stated, in support of the rejection that Tsuruta discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope. Claims 39 and 44-50 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Bessler. The Examiner stated, in support of the rejection that Sauer discloses the invention substantially as claimed except for the internal endoscope, but that Bessler shows such an endoscope.

Claim 44 recites “an operating head including a coupling structure for selectively coupling to the endoscope, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained, wherein the anvil and the stapling mechanism are permanently coupled to one another,” in combination with “a flexible grasping mechanism extending through the sheath for drawing tissue into a space between the stapling mechanism and the anvil.”

For the reasons stated above in regard to claim 36, it is respectfully submitted that neither Tsuruta nor Sauer either shows or suggests a system including “*a flexible endoscope*” and “an operating head including *a coupling structure for selectively coupling to the endoscope*,” as recited in claim 44.

As stated above in regard to claim 39, the rigid devices of Sauer and Tsuruta are for very different applications (i.e., open surgery) than the claimed device and these differences teach away from combinations with flexible endoscopes. Thus, none of the references provides the motivation for such a combination. Furthermore, as discussed above, combining the teaching of

Bessler with any rigid device is completely contradictory to the teachings of that reference is clearly taught away from by Bessler.

Furthermore, it is respectfully submitted that Bessler describes a device which must necessarily be used in conjunction with open surgery and that the device includes no grasper mechanism for drawing tissue into a space between the anvil and the stapling mechanism. Rather, the tubular organ which is to be anastomosed is severed and the severed ends of this organ are positioned around the anvil member 52 and the stapling head assembly 50 through open surgery. (Col. 8, lines 39 - 53). No mechanism for performing this cutting operation or for positioning the cut ends of the organ is included in the device of Bessler. Nor would such a mechanism serve any purpose in this device as external surgery is required to sever the organ and then to place to two separated halves of the stapling head (i.e., the stapling mechanism 50 and the anvil member 52) on opposite sides of the cut through the organ. (See Fig. 4).

Thus, it is respectfully submitted that the cited references neither show nor suggest a system including a flexible grasping mechanism as recited in claim 44 and that none of the cited references provides any motivation for the combination suggested by the Examiner.

Therefore, it is respectfully submitted that claim 44 is not rendered obvious by Tsuruta, Sauer and Bessler either taken alone or in combination and this rejection should be withdrawn. Because claims 45 - 48 depend from and include all of the limitations of claim 44, it is submitted that these claims are also allowable.

Claims 39 and 44 - 48 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Bessler. The Examiner stated, in support of the rejection, that Sauer shows the invention as claimed except for the use of an internal endoscope and that Bessler shows the endoscope as claimed.

As stated above in regard to the prior rejections of claims 36 and 44, Sauer shows a rigid device unsuitable for use with a flexible endoscope and in any case inconsistent with the

recitations of amended claims 36 and 44.

Specifically, it is respectfully submitted that Sauer teaches away from both “an operating capsule including *a coupling structure for selectively coupling to a flexible endoscope*, the operating capsule being sized so that, when in an operative position entirely located within a body lumen adjacent to a selected portion of tissue to be resected structural integrity of luminal tissue is maintained, the operating capsule including a suturing assembly and defining a cutting zone adjacent to the suturing assembly,” in combination with “a flexible member extending proximally from the operating capsule to a control handle, wherein, when the operating capsule is in an operative position within a body lumen, the flexible member extends through the body and out a natural body orifice to the control handle; as recited in claim 36 and “an operating head including *a coupling structure for selectively coupling to the endoscope*, the operating head including an anvil and a stapling mechanism moveable with respect to one another between a closed position in which the anvil and the stapling mechanism are adjacent to one another and a tissue receiving position in which the anvil is separated from the stapling mechanism, *the operating head being sized so that, when in an operative position entirely located within a body lumen, structural integrity of luminal tissue is maintained,*” as recited in claim 44. Furthermore, it is respectfully submitted that Bessler does not cure these defects and, in any case, neither reference provides motivation for the combination.

Claims 49 - 51 stand rejected under 35 U.S.C. § 103 as obvious over Sauer in view of Kessel (DE Publication No. 4,006,673). The Examiner stated, in support of the rejection, that Sauer shows the invention as claimed with the exception of the advancing of the head over a flexible endoscope but that Kessel shows the relative sliding of a scope and forceps.

Claim 49 recites a method for resecting tissue from within a body lumen, comprising the steps of “inserting an operating head coupled to a flexible endoscope into a body lumen *via a naturally occurring body orifice*, wherein the operating head includes an anvil and a stapling mechanism” and “advancing the operating head over the endoscope within the body lumen to a desired position relative to a selected portion of tissue to be resected, wherein, *when in the*

desired position, the entire operating head is located within the body lumen with the flexible endoscope bending to substantially conform to an unstressed configuration of the body lumen."

As stated above in regard to the rejections of claims 36 and 44, it is respectfully submitted that the rigidity of the Sauer device makes it wholly unsuitable for practicing the claimed method. Specifically, whether or not the Sauer device were coupled to a flexible endoscope as suggested by the Examiner, the rigidity of the device would make it impossible to insert the device into a body lumen via a naturally occurring body orifice to a point where an operating head of the device is entirely received within the body lumen. It is respectfully submitted that Kessler suggests nothing to cure this defect and that neither reference supplies motivation to one of skill in the art to make the proposed combination.

It is therefore respectfully submitted that amended claim 49 is not rendered obvious by Sauer and Kessler whether taken alone or in combination and that this rejection should be withdrawn.

It is respectfully submitted that all of the presently pending claims are allowable and that the present application is in condition for allowance. Therefore, a prompt and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned at (212) 619-6000, ext. 202 to discuss any matter concerning this application.

Respectfully submitted,

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